3. The r combinant vaccinia virus according to claim 1, wh rein the gen includes nucleotid sequence of GAD65 or its analogs.

4. The recombinant vaccinia virus according to claim 1, wherein the virus includes a recombinant DNA molecule which is formed by cloning the gene for coding glutamic acid decarboxylase into a plasmid vector.

REMARKS

In accordance with the foregoing, the specification and claims 3 and 4 have been amended. Claims 1-11 are pending and under consideration.

The specification on page 3 line 6 has been amended, to overcome the Examiner's objection. Page 3 line 6 now refers to the inventor as "we" instead of "I".

In accordance with the Notice to Comply regarding the "Sequence Listing", the following are enclosed herewith: (1) a paper copy of a Sequence Listing entitled "sequence2.ST25" generated using PatentIn version 3.1 and corresponding to the sequences included in the subject application; (2) a diskette including a file entitled "sequence2.ST25.txt" corresponding to (1), above, in computer-readable format, and also generated using PatentIn version 3.1; and (3) a statement Regarding Sequence Listings stating that the Sequence Listing submitted is in accordance with 37 C.F.R. §§ 1.821(c) and (e) and 1.825 and that the content of the paper and computer readable copies of the Sequence Listing are the same. The statement further includes that this submission, is filed in accordance with 37 C.F.R. §1.821(g), and does not include new matter. The entry of the Sequence Listing is respectfully requested.

Claim 4 has been amended to overcome the Examiner's objection to claims 4 through 6, of page 3 of the Office Action, under 35 U.S.C. §112, second paragraph.

Claim 2 at pages 3 through 4 of the Office Action, is rejected under 35 U.S.C. §112, first paragraph. The Examiner indicates that an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. We have attached a declaration to such effect corresponding to 37 C.F.R. §1.802 in order to overcome the rejection of claim 2.

Claims 1 through 3 and 7 through 11, at pages 4 through 5 of the Office Action, according to the Examiner, are rejected under 35 U.S.C. §103(a) as being unpatentable over Muir et al.

(U.S. Patent No. 5,891,435). Muir et al. only discloses that the vaccinia virus can be used to express numerous viral antigens. The suitability of a virus for expressing a foreign antigen should be confirmed by experimental tests. However, the specific cloning of GAD 65 with the vaccinia virus, and its experimental test results are not disclosed in Muir et al.

In addition, at pages 5 through 6 of the Office Action, claims 4 through 6, according to the Examiner, are rejected under 35 U.S.C. §103(a) as being unpatentable over Muir et al. as applied to claims 1 through 3, and 7 through 11, and further in view of Moss (Moss et al. Nucleic Acids Research 1990, 18:4285-4286). Muir does not disclose or teach the specific cloning of GAD 65 with the vaccinia virus and its experimental test results and also Moss et al. only teaches that the plasmid PMJ 601 can be used to generate vaccinia virus recombinants for expressing foreign proteins with high level. Muir and Moss do not teach the specific recombinant DNA molecule formed by cloning the GAD 65 cDNA into the PMJ 601. Furthermore, the success of the specific combination by cloning the GAD 65 cDNA into the PMJ 601, cannot be expected without extensive experimentation.

Therefore, it is deemed that the present invention is not obvious in view of the cited prior art, wherein neither Muir or Moss disclose the specific combinations of GAD 65 cDNA, PMJ 601 and the vaccinia virus, and the experimental test results thereof.

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance. An early action to that effect is courteously solicited.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned to attend to these matters.

If there are any additional fees associated with filing of this Amendment, please charge the same to our Deposit Account No. 19-3935.

Respectfully submitted,

STAAS & HALSEY LLP

Date: 7/1/02

By: _____
Michael D. Stein
Registration No. 37,240

700 Eleventh Street, NW, Suite 500
Washington, D.C. 20001
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CERTIFICATE UNDER 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231

on July 1, 2002

STAAS & HALSEY LLP

By: _____

Date: July 1, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Please REPLACE the paragraph beginning at page 3, line 5, as follows:

In view of the foregoing and to explore the potential of immunogene therapy based on GAD for the prevention of autoimmune diabetes, [I] we developed a recombinant virus which can express GAD and induce humoral and cell-mediated immune response to a target protein, and found that the induced immune responses are long lived.

IN THE CLAIMS:

Please AMEND the following claims:

1. (AS UNAMENDED) A recombinant vaccinia virus incorporated with a gene for coding glutamic acid decarboxylase.

2. (AS UNAMENDED) The recombinant vaccinia virus according to claim 1, wherein the vaccinia virus is a virus of deposit number ATCC VR-1354.

3. (AS ONCE AMENDED) The recombinant vaccinia virus according to claim 1, wherein the gene includes nucleotide sequence of GAD65 or its [analogous] analogs.

4. (AS ONCE AMENDED) The recombinant vaccinia virus according to claim 1, wherein the virus includes a recombinant DNA molecule which is formed by cloning the gene for coding glutamic acid decarboxylase into a plasmid vector [gene is cloned into a plasmid vector to form a recombinant DNA molecule].

5. (AS UNAMENDED) The recombinant vaccinia virus according to claim 4, wherein the plasmid vector is pMJ601.

6. (AS UNAMENDED) The recombinant vaccinia virus according to claim 4, wherein the recombinant DNA molecule includes a gene coding for Thymidine Kinase left region, pLsyn, GAD65 cDNA, a gene coding for β-galactosidase, and a gene coding for Thymidine Kinase right region.

7. (AS UNAMENDED) A vaccine for preventing or delaying the type 1 diabetes mellitus

comprising a recombinant vaccinia virus incorporated with a gene for coding glutamic acid decarboxylase.

8. (AS UNAMENDED) The vaccine for preventing or delaying the type 1 diabetes mellitus according to claim 7, further comprising pharmaceutically allowable additives.

9. (AS UNAMENDED) The vaccine for preventing or delaying the type 1 diabetes mellitus according to claim 8, wherein the additives includes one or more stabilizer selected form the group consisting of fetal serum albumin, lactose, sugar, formalin, gelatin, polysorbate 80, aminoacetic acid, cysteine, ethylenediaminetetra aceticacid, and sodium glutamate.

10. (AS UNAMENDED) The vaccine for preventing or delaying the type 1 diabetes mellitus according to claim 8, wherein the additives includes one or more preserving agent selected form the group consisting of thimerosal, sulfuric acid Kanamycin, erythromycin, streptomycin, phenol and neomycin.

11. (AS UNAMENDED) The vaccine for preventing or delaying the type 1 diabetes mellitus according to claim 7, wherein the effective amount of the vaccine is in the range of $1x10^3$ ~ $1x10^{11}$ PFU.

Attorney Docket No. 1546.1007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Ji-Won YOON et al.

Application No.: 09/995,829 Group Art Unit: 1648

Filed: November 29, 2001 Examiner: M. Mosher

For: RECOMBINANT VACCINIA INCORPORATED WITH GENE CODING GLUTAMIC ACID DECARBOXYLASE AND VACCINE FOR PREVENTING TYPE 1 DIABETES MELLITUS COMPRISING THE SAME

DECLARATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure provisions of 37 CFR § 1.802, the deposit has been made under the terms of the Budapest Treaty and all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent. It is requested that the Examiner make this information of record if it is deemed material to the examination of the subject application.

I hereby state that the content of the paper and computer readable copies of the Sequence Listing, submitted in accordance with 37 C.F.R. §§ 1.821(c) and (e) and 1.825 respectively are the same.

I hereby state that this submission, filed in accordance with 37 C.F.R. §1.821(g), does not include new matter.

Respectfully submitted,

STAAS & HALSEY LLP

Dated: 7/1/02

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CERTIFICATE UNDER 37 CFR 1.8(a)

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on July 1, 2002

STAAS & HALSEY LLP

By: _____

Date: July 1, 2002